



Fact Sheet

United States Nuclear Regulatory Commission
Office of Public Affairs
Washington DC 20555
Telephone: 301/415-8200 E-mail: opa@nrc.gov

Medical Use of Radioisotopes

Background

The Nuclear Regulatory Commission's mandate to protect public health and safety and the environment includes regulation of the medical use of byproduct material in the fields of nuclear medicine, radiation therapy, and research.

Medical use of radioisotopes and radiation falls broadly into two categories: diagnostic and therapeutic. Diagnostic procedures using radioisotopes and radiation are classified as either radiology (sources used external to the body) or nuclear medicine (sources internal to the body). Both involve the use of relatively small amounts of radioactive materials or radiation to facilitate imaging of a suspected medical problem. For the most part, radiology is the use of x-ray machines as an external source of radiation for imaging. Two examples of nuclear medicine are the use of technetium-99m in the diagnosis of bone or heart organ problems and radioactive iodine in the imaging of the thyroid gland. The radioisotopes are injected into the patient and allow physicians to locate and identify tumors, size anomalies, or other problems.

Therapeutic uses of radionuclides include teletherapy, brachytherapy, and therapeutic nuclear medicine. The purpose of all three is to kill cancerous tissue, reduce the size of a tumor, or reduce pain. In **teletherapy**, an intense beam of radiation, from a source external to the patient, is focused on the tissue. An example of teletherapy is the use of the Gamma Knife, which uses a collimating helmet to focus gamma rays from cobalt-60 sources to a specific location deep within brain tissue.

In **brachytherapy**, a smaller source is placed close to, or within, cancerous tissue where the tumor is easily accessible, such as in breast, prostate, or cervical cancers. The sources are sealed "seeds" injected or surgically implanted then removed after the prescribed dose is received by the patient.

In **therapeutic nuclear medicine**, high doses of radionuclides are injected into, or ingested by, the patient. One example is the use of radioactive iodine to destroy or shrink a diseased thyroid.

The radioisotopes or sources of radiation are either byproduct material (nuclear material produced in a reactor), accelerator produced nuclear material, or radiation producing machines such as x-ray machines. Regulatory authority over the use of byproduct materials and other sources of ionizing radiation in medicine is shared among several government agencies at the Federal, State, and local levels. Byproduct material is regulated by either the NRC or by thirty-two states, known as Agreement States (these are states that have entered into an agreement with the NRC to regulate the use of byproduct material). These states issue licenses and currently regulate approximately 4,800 medical-use licenses, such as university medical centers, hospitals, clinics, and

physicians in private practice. The NRC regulates the medical use of byproduct material in 18 non-agreement states, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States and administers approximately 1,800 medical-use licenses.

The Food and Drug Administration (FDA) oversees approval of radiation-producing machines and radiopharmaceuticals. Radiation-producing machines such as x-ray machines and accelerator produced radioisotopes are regulated by the States.

Discussion

The NRC and its predecessor, the Atomic Energy Commission, have regulated the medical use of radioisotopes since 1946. The NRC regulates medical uses of radioisotopes under Part 35, "Medical Use of Byproduct Material" in Title 10 of the Code of Federal Regulations. The purpose of NRC regulation of medical use is to prevent needless radiation exposures of both patients and medical workers while not interfering with treatment protocols established by the physician. This is the basis of the Medical Use Policy Statement, published in the Federal Register on August 3, 2000. The Policy indicates that the NRC will:

- (1) continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public;
- (2) not intrude into medical judgements affecting patients, except as necessary to provide for the radiation safety of workers and the general public;
- (3) when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of the radionuclides is in accordance with the physicians' directions; and
- (4) in developing a specific regulatory approach, consider industry and professional standards that define acceptable approaches of achieving radiation safety.

The NRC oversees medical use of radioisotopes through licensing, inspection, investigation, and enforcement programs. The NRC issues licenses to facilities, authorizes physician users, develops appropriate regulations and guidance for use by licensees. The NRC maintains the Advisory Committee on the Medical Use of Isotopes (ACMUI), a committee of medical experts to obtain advice in the use of byproduct materials in medicine. The ACMUI meets twice a year to be briefed by, and provide advice to, the NRC staff on current initiatives in medical use of radioactive materials. The committee consists of physicians specializing in all areas of diagnostic and therapeutic medical use of byproduct materials. Members include a nuclear pharmacist, a medical physicist, a patient advocate, a health care administrator, and a radiation safety officer.

Memorandum of Understanding between NRC and FDA

On April 2, 1997, a Federal Register notice was published renewing an earlier Memorandum of Understanding between FDA and NRC. It clarifies the respective roles of each agency in regulating the safe use of radiopharmaceutical and sealed sources, or devices containing byproduct material. As a result, NRC and FDA have established liaison officers and identified key management and technical personnel for coordinating responses to emergencies or specific events of mutual interest. Additionally, NRC and FDA have conducted joint inspections of medical events involving device failures and human or computer-generated errors. Senior management meetings between the two agencies have been conducted annually.

Recent Activities

A major revision to 10 CFR Part 35, "Medical Use of Byproduct Material," was approved by the Nuclear Regulatory Commission on October 23, 2000. The rule will be published in the Federal Register early in 2001 and will become effective six months after publication. The revision is part of the NRC's effort to use more risk insights in its regulations and inspections. The revised rule focuses on those procedures that pose the highest risk and on those requirements that are essential for protecting patient safety. The NRC Medical Use Policy Statement was revised as part of this rule and was published in the Federal Register on August 3, 2000. More information on the rule can be found at the Medical Use of Byproduct Material Rulemaking web site: http://ruleforum.llnl.gov/cgi-bin/rulemake?source=MU_PRULE

November 2000